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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/368,076 08/03/99 JIN

H 7682-047

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HM22/0723

EXAMINER

BRUMBACK, B

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

07/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/368,076

Applicant(s)

Hong et al.

Examiner

Brenda Brumback

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 9, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group I, claims 1-12 in Paper No. 11 is acknowledged. Claims 13-35 have been canceled. Claims 1-12 are pending and under examination.

Specification

2. The preliminary amendment filed 11/30/2000 is acknowledged; however, the amendments to the specification are too extensive for manual entry. A substitute specification excluding claims is required pursuant to 37 CFR 1.125(a).

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

Additionally, in the substitute specification, applicant should amend the Description of the Figures to incorporate a listing of all figures labeled with letter designations; *i.e.*, FIG.4 should be

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amended to FIG 4A-C, FIG. 6 should be amended to FIG. 6A-B, FIG. 12 should be amended to FIG. 12A-B, etc.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it claims benefit of Provisional Application Number 60/069,153, which is by a different inventive entity and which is drawn to completely unrelated subject matter. Prior to submission of the new declaration, applicant may wish to review the Provisional Application Number for a possible typographical error.

Priority

4. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, Provisional Application numbers 60/069,153 and 60/084,133 upon which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for claims 1-12 of this application. For purposes of examination, priority has been established as 06/12/1998, as the present claims are supported by Provisional Application Number 60/089,207, filed 06/12/98.

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Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claimed invention is drawn to an isolated infectious respiratory syncytial virus (RSV) particle comprising a genome or antigenome with at least one functional deletion in a viral accessory gene or a mutation in either a single gene selected from M2-2, SH, NS1, and NS2; or mutations in a combination of any two of those genes; or a combination of mutations in the NS1, NS2, and SH genes.

Claims 1-12 are rejected under 35 U.S.C. 102(a) as being anticipated by Murphy et al. (WO 98/02530; hereinafter Murphy '530). Murphy '530 teaches isolated RSV particles comprising a RSV genome or antigenome containing deletions or mutations in any of the M2 ORF2, SH, NS1 or NS2 viral accessory genes or any combination of the M2 ORF2, SH, NS1 and NS2 genes. Murphy '530 teach that mutations or deletions in those genes result in enhanced attenuation, genetic resistance to reversion from an attenuated phenotype, and increased yield of

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virus (see the abstract, page 9 lines 6-38; page 10, lines 1-7; page 17, lines 24-27; page 29, line 20 through page 30 line 3; page 36, lines 10-18; and page 40, lines 2-21).

Claims 1-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Murphy et al. (U.S. Patent 5,993,824; hereinafter Murphy '824). Murphy '824 teaches attenuated RSV particles comprising specific mutations or deletions in any of the M2 ORF2, SH, NS1 or NS2 viral accessory genes or any combination of the M2 ORF2, SH, NS1 and NS2 genes. Murphy et al. teach that mutations in or deletions of one or more of the genes result in enhanced growth in tissue culture (the SH gene deletion), enhanced attenuation, and enhanced genetic resistance to reversion from an attenuated phenotype (see the abstract; column 5, lines 18-25 and 54-57; column 6, lines 1-43; column 17, lines 33-36; column 18, lines 9-16 and 26-28).

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Collins (WO 97/12032). Collins teaches isolated infectious RSV particles comprising mutations or functional deletion (ablation) of the NS1, NS2, SH, and/or M2(ORF2) genes. Collins teaches that such mutations and deletions can be used for analyzing RSV molecular biology and pathogenesis (see page 16, lines 10-16).

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Bukreyev et al. teach that RSV from which the SH gene has been deleted grows efficiently in tissue culture and is immunogenic (see the abstract).

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB

July 20, 2001


Brenda Brumback,
Patent Examiner